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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/015,540	12/11/2001	Nicholas Ling	690068.405C3	4186
500	7590	12/02/2003	EXAMINER	
SEED INTELLECTUAL PROPERTY LAW GROUP PLLC			BORIN, MICHAEL L	
701 FIFTH AVE			ART UNIT	
SUITE 6300			PAPER NUMBER	
SEATTLE, WA 98104-7092			1631	

DATE MAILED: 12/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/015,540	Applicant(s) LING ET AL.	
	Examiner Michael Borin	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 30-34,45,46,48-50,73 and 74 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 30-34,45,46,48-50,73 and 74 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1631

DETAILED ACTION

Status of Claims

1. Response to restriction requirement and Preliminary amendment filed 09/15/2003 is acknowledged. Preliminary amendment of claim 45 renders the restriction requirement moot. Therefore, all pending claims, claims 30-34,45,46,48-50, 73,74 are examined.

Information Disclosure Statement

2. Applicants' Information Disclosure Statement filed 03/04/02 has been received and entered into the application. Accordingly, as reflected by the attached completed copies of forms PTO-1449, the cited references have been considered.

Sequence Listing

3. The Sequence Listing filed 03/06/2002 was approved by STIC for matters of form.

Examiner appreciates explanation provided in regard to SEQ ID No. 3.

Art Unit: 1631

Claim Rejections - 35 USC § 112, second paragraph.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 30-34,74 are rejected under 35 U.S.C. 112, second paragraph, for failing to particularly point out and distinctly define the metes and bounds of the subject matter that will be protected by the patent grant . The definition "*in vivo* proteolysis" is vague and unclear; it does not define the scope of the functional limitation as the conditions for *in vivo* proteolysis vary widely.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 30-34, 73,74 are rejected under 35 U.S.C. 102(b) as being anticipated by Bellacosa et al (Science, 254 (5029), 274-7, 1991; reference BG) or Pautot et al (Proc. Natl. Acad. Sci., 90 (21) 9906-9910, 1993; reference EG).

Art Unit: 1631

Bellacosa describes vAkr peptide containing amino acid sequence RFFANIVW at positions 689-697 (Fig. 2). The referenced compound reads on the instantly claimed fragment SEQ ID No. 3 in which Lys 91 is replaced with Ala, and N- and C-termini of the fragment are altered.

Paudot teaches peptides containing the sequence LVNAPANIVTPAVL at positions 159-172.

The referenced peptides read on peptides of claims 30,32,33 wherein Lys-91 residue is replaced with Ala, and wherein N- and C-termini are modified. Further, the referenced peptides read on peptides claimed in claim 73 wherein Lys-91 is replaced with Ala and residues in positions 86-90 and 97-99 are replaced.

Further, in regard to claims 31,33, the difference of the peptide analogs to which the specified claims are drawn is that they comprise D-analogs of particular amino acid residues. An optically active isomer is unpatentable over a prior art optical isomer of opposite rotation in the absence of unexpected or unobvious beneficial properties. In re Adamson et al., 125 USPQ 233 (CCPA 1960). Therefore, the instantly claimed compounds are anticipated. Note, that claims 3, 4, 9, 10, 13, 14, 16, 17, 19, 20, 23, 24, 26, 27, 29 drawn to D-isomer substitutions, which are proved by the presented working examples and drawings to be beneficial for inhibitory effect of peptide analogs, are not included in the rejection. Note, further, that a

Art Unit: 1631

substitution L- to D-isomers can not be assumed beneficial by default, because Teitelbaum et al. (Proc. Natl. Acad. Sci. USA, 85, 9724-9728, 1988; reference GI) teach that substitution of L- to D-isomer may not be beneficial for inhibitory effect of a peptide analog; on the contrary, it may abolish the inhibitory effect (see p. 9727, end of para. 2).

In regard to functional limitation of claims 30-34, when the reference discloses all the limitations of a claim except a property or function, and the examiner cannot determine whether or not the reference inherently possesses the properties which anticipate or render obvious the claimed invention, the burden of proof shifts to applicant. *In re Fitzgerald et al.* 619 F.2d 67, 205 USPQ 594, (CCPA 1980). The reference teaches the peptide that meets the structural limitation claimed. Although the reference does not teach the functional limitation of the peptide, such a limitation would be inherent in the peptide since it meets the structural limitations of the claim. A reference which is silent about a claimed invention's feature is inherently anticipatory if the missing feature is necessarily present in that which is described in the reference. *In re Oelrich*, 212, USPQ 323 (CCPA 1981). Where the claimed and prior art products are identical or substantially identical in structure or composition, a prima facie case of either anticipation or obviousness has been established. *In re Best*, 195 USPQ 430, 433 (CCPA 1977).

Art Unit: 1631

6. Claims 45,46,48-50,74 are rejected under 35 U.S.C. 102(a) as being anticipated by Wucherpfenig et al. (J. Exp. Med., 179, 279-290; reference HC). Wucherpfenig teaches peptide analogs comprising residues of 84-102 fragment of MBP with Ala substitutions of one of the residues selected from the residues at positions 86-97. In particular, analog (85-99)93A (Table 4) reads on instantly claimed peptides wherein Lys-91 is substituted with Ala.

In regard to claim 49, the difference of the peptide analogs to which the specified claims are drawn is that they comprise D-analogs of particular amino acid residues. An optically active isomer is unpatentable over a prior art optical isomer of opposite rotation in the absence of unexpected or unobvious beneficial properties. In re Adamson et al., 125 USPQ 233 (CCPA 1960). Therefore, the instantly claimed compounds are anticipated. Note, that claims 3, 4, 9, 10, 13, 14, 16, 17, 19, 20, 23, 24, 26, 27, 29 drawn to D-isomer substitutions, which are proved by the presented working examples and drawings to be beneficial for inhibitory effect of peptide analogs, are not included in the rejection. Note, further, that a substitution L- to D-isomers can not be assumed beneficial by default, because Teitelbaum et al. (Proc. Natl. Acad. Sci. USA, 85, 9724-9728, 1988; reference GI) teach that substitution of L- to D-isomer may not be beneficial for inhibitory effect of a peptide

Art Unit: 1631

analog; on the contrary, it may abolish the inhibitory effect (see p. 9727, end of para. 2).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 31,33 or claim 49 are rejected under 35 U.S.C. § 103 as being unpatentably obvious over Bellacosa/Pautot or Wucherpfenig et al. as applied to claims 30-34 or claims 45,46, 48-50, respectively and in view of Nishimoto et al. (US Patent 5,529,209; reference AC). Application of primary references is as discussed above. Nishimoto teaches that the replacement of an L-amino acid residue with the corresponding D- isomer is a standard way of rendering the polypeptide less sensitive to proteolysis. See col. 15, line 2. It would have been obvious to an artisan at the time the invention was made to alter the terminal amino acid residues of MBP peptide

Art Unit: 1631

analogous from L- to D-isomers to reduce proteolysis and thus to extend the desired inhibitory effect.

Double Patenting

8. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

9. Claim 34 is rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 7 of prior U.S. Patent No. 6,329,499. This is a double patenting rejection.

Art Unit: 1631

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claims 30-34, 45,46,48-50, 73, 74 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1,2,7 of U.S. Patent No. U.S. Patent No. 6,329,499. Although the conflicting claims are not

Art Unit: 1631

identical, they are not patentably distinct from each other because the claims of U.S. Patent No. 6,329,499. are drawn to peptides with substituted Lys-91, and, optionally N-C-terminal residues (claim 7) or other residues (claims 1,2).

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (703) 305-4506. Dr. Borin can normally be reached between the hours of 8:30 A.M. to 5:00 P.M. EST Monday to Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Michael Woodward, can be reached on (703) 308-4028. The fax telephone number for this group is (703) 305-3014.

Any inquiry of a general nature or relating the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

November 25, 2003

mlb

MICHAEL BORIN, PH.D.
PRIMARY EXAMINER

